UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

SCIELE PHARMA, INC. and SCIELE PHARMA CAYMAN LTD.,	)	Civil Action No. 07-00664
Plaintiffs,	)	
v.	)	**JURY TRIAL DEMANDED**
MYLAN PHARMACEUTICALS, INC. and MYLAN LABORATORIES, INC.,	)	
Defendants.	)	

ANSWER, DEFENSES, AND COUNTERCLAIM

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Mylan Pharmaceuticals, Inc. and
Mylan Laboratories, Inc.

December 18, 2007

Defendants Mylan Pharmaceuticals, Inc. ("Mylan Pharms") and Mylan Laboratories, Inc. (now known as Mylan Inc.)(collectively, "Mylan") hereby answer the Complaint of Plaintiffs Sciele Pharma, Inc. and Sciele Pharma Cayman Ltd. (collectively, "Sciele"), as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent No. 4,892,741 ("the '741 patent") under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that this action purports to be for alleged patent infringement under 35 U.S.C. § 271(e)(2)(A). Mylan denies that Sciele has standing to assert, or that this Court has subject matter jurisdiction to adjudicate, such a claim.

The Parties

2. Plaintiff Sciele Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 5 Concourse Parkway, Suite 1800, Atlanta, Georgia 30328.

ANSWER: Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

3. Plaintiff Sciele Pharma Cayman Ltd. is a corporation organized and existing under the laws of the Cayman Islands with a principal place of business at Ugland House, South Church Street, Georgetown, Grand Cayman, Cayman Islands.

ANSWER: Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

4. On information and belief, defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

ANSWER: Admitted.

5. On information and belief, Mylan Pharmaceuticals manufactures and sells numerous generic pharmaceutical products for use throughout the United States, including this judicial district.

ANSWER: Mylan admits that Mylan Pharms develops, manufactures and sells quality generic medicines. Mylan denies the remaining allegations of this paragraph.

6. On information and belief, defendant Mylan Laboratories, Inc. ("Mylan Laboratories") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317.

ANSWER: Mylan admits that Mylan Inc. (formerly known as Mylan Laboratories, Inc.) is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317. Mylan denies the remaining allegations of this paragraph.

7. On information and belief, Mylan Laboratories is the parent company of Mylan Pharmaceuticals, and Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Laboratories.

ANSWER: Mylan admits that Mylan Inc. (formerly known as Mylan Laboratories, Inc.) is the parent company of Mylan Pharms. Mylan denies the remaining allegations of this paragraph.

8. On information and belief, Mylan Pharmaceuticals and Mylan Laboratories collaborate in the manufacture, marketing, and sale of many generic pharmaceutical products, including numerous products that are marketed and sold in Delaware.

ANSWER: Denied.

9. Mylan Laboratories states in its 2007 Annual Report that "Mylan Pharmaceuticals, Inc., Mylan's flagship generic subsidiary, once again ranked as one of the nation's leading providers of pharmaceutical products overall, and pharmacists filled over 257 million prescriptions with products from Mylan." On information and belief, a proportionate number of those prescriptions were filled in Delaware.

ANSWER: Mylan admits that Paragraph 9 purports to recite, out of context, a statement from Mylan Laboratories, Inc.'s 2007 Annual Report. Mylan denies the remaining allegations of this paragraph.

Jurisdiction and Venue

10. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

ANSWER: Denied.

11. Based on the facts and causes alleged herein, this Court has personal jurisdiction over defendants Mylan Pharmaceuticals and Mylan Laboratories.

ANSWER: Paragraph 11 contains legal conclusions to which no response is required. To the extent a response is required, to conserve the resources of the parties and Court, Mylan does not contest personal jurisdiction for purposes of this lawsuit only. Mylan denies the remaining allegations of this paragraph.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, to conserve the resources of the parties and Court, Mylan does not contest venue for purposes of this lawsuit only. Mylan denies the remaining allegations of this paragraph.

Background

13. The '741 patent, entitled "Press Coated DHP Tablets," issued on January 9, 1990 to Andreas Ohm, Helmut Luchtenberg, Shinji Maegata and Wolfgang Opitz. A copy of the '741 patent is attached to this complaint as Exhibit A.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that, according to the electronic records of the

U.S. Patent and Trademark Office ("PTO"), on or about January 9, 1990, the PTO issued the '741 patent, entitled "Press Coated DHP Tablets," to Andreas Ohm, Helmut Luchtenberg, Shinji Maegata and Wolfgang Opitz; that what purports to be a copy of the '741 patent is attached to the Complaint as Exhibit A; and that, according to the electronic records of the PTO, the '741 patent is owned by and assigned to Bayer Healthcare AG. Mylan denies that Sciele has standing to assert, or that this Court has subject matter jurisdiction to adjudicate, any claim for alleged infringement of the '741 patent. Mylan denies the remaining allegations of this paragraph.

14. Sciele is the exclusive licensee of the '741 patent and possesses all substantial rights in the '741 patent, including the right to enforce the patent.

ANSWER: Denied. Mylan further denies that Sciele has standing to assert, or that this Court has subject matter jurisdiction to adjudicate, any claim by Sciele for alleged infringement of the '741 patent.

15. Sciele is the holder of approved New Drug Application ("NDA") No. 20-356 for nisoldipine extended release tablets in 10mg, 20mg, 30mg, and 40mg dosages, all sold under the Sular® trademark.

ANSWER: Mylan admits that the electronic version of the U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (current through October 2007) (commonly known as the "Orange Book"), identifies "SCIELE PHARMA INC" as the applicant for approved New Drug Application ("NDA") No. 20-356 for nisoldipine extended release tablets in 10mg, 20mg, 30mg, and 40mg dosages. Mylan denies the remaining allegations of this paragraph.

16. In conjunction with NDA No. 20-356, Sciele has listed the '741 patent, which covers various aspects of the approved formulations of Sular®, in the Orange Book.

ANSWER: Paragraph 16 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that FDA's Orange Book

lists the '741 patent in connection with NDA No. 20-356 for Sular®. Mylan denies the remaining allegations of this paragraph.

17. On September 10, 2007, Sciele received a letter ("Paragraph IV Letter"), dated September 7, 2007, signed on behalf of Mylan. The Paragraph IV Letter represented that Mylan had filed Abbreviated New Drug Application No. 79-051 ("ANDA No. 79-051") with the United States Food and Drug Administration ("FDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to engage in the commercial manufacture, use, or sale of a proposed generic version of Sciele's Sular® tablets 40mg, before the expiration of the '741 patent.

ANSWER: Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that Mylan Pharms has submitted an ANDA to FDA seeking approval to commercially manufacture, use or sell nisoldipine extended release tablets 40 mg; and that, in a letter dated September 7, 2007, entitled "Notification of Paragraph IV Certification Regarding U.S. Patent No. 4,892,741 – Mylan Pharmaceuticals, Inc. ANDA No. 79-051 for Nisoldipine Extended Release Tablets 40 mg," Mylan Pharms duly notified, among others, the actual patent owner (Bayer Healthcare AG) and Sciele that Mylan Pharms had filed an ANDA with a so-called "paragraph IV certification" seeking to obtain approval to engage in the commercial manufacture, use or sale of nisoldipine extended release tablets 40 mg prior to the expiration of the '741 patent. Mylan denies the remaining allegations of this paragraph.

18. The Paragraph IV Letter also stated that ANDA No. 79-051 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '741 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan's proposed generic version of Sciele's Sular® tablets 40mg.

ANSWER: Mylan admits that Mylan Pharms' ANDA contains a paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), stating that the '741 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan Pharms' nisoldipine extended release tablets 40 mg that are the subject of its ANDA. Mylan denies the

remaining allegations of this paragraph.

19. Mylan's Paragraph IV Letter claims that Mylan's proposed generic version of 40 mg Sular® would not infringe the '741 patent, but contains extremely limited information about that proposed generic version. For example, although the Letter purports to list various ingredients in the proposed generic version, it does not list the amounts of the various ingredients or provide any information about the method by which the proposed generic version is manufactured. In total, the Letter contains fewer than 15 lines of information about Mylan's proposed generic version of 40 mg Sular®.

ANSWER: Mylan admits that Mylan Pharms' notification letter fully complies with all statutory and regulatory requirements and sets forth the factual and legal bases for Mylan Pharms' paragraph IV certification that the '741 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan Pharms' nisoldipine extended release tablets 40 mg that are the subject of its ANDA. Mylan denies the remaining allegations of this paragraph.

20. Along with the Paragraph IV Letter, Mylan sent to Sciele a document entitled "Offer of Confidential Access to ANDA No. 79-051" that it requested Sciele sign before providing access to any portion of Mylan's ANDA No. 79-051. This document contained various restrictions on who could view the ANDA that effectively eliminated Sciele's ability to meaningfully access ANDA No. 79-051 and process the information contained therein. For example, this Offer barred any access to in-house counsel, and substantially limited the fields of practice of outside counsel who might view the ANDA.

ANSWER: Mylan admits that Mylan Pharms duly provided the patent owner (Bayer Healthcare AG) and Sciele with a good faith "Offer of Confidential Access" ("OCA") to Mylan Pharms' ANDA; that Mylan Pharms' good faith OCA was reasonable and complied with all statutory and regulatory requirements; and that Sciele rejected Mylan Pharms' good faith OCA. Mylan denies the remaining allegations of this paragraph.

21. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

ANSWER: Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that Mylan Pharms' good faith OCA was reasonable and complied with all statutory and regulatory requirements. Mylan denies the remaining allegations of this paragraph.

22. Since receiving the Paragraph IV Letter and the accompanying "Offer of Confidential Access," Sciele has attempted to negotiate with Mylan to procure a copy of ANDA No. 79-051 under restrictions "as would apply had a protective order been issued." These negotiations have been unsuccessful. For example, while Mylan relented to allowing in-house counsel to see the ANDA in theory, Mylan limited the qualifications of such individuals to such an extent that no qualified Sciele in-house personnel could actually review the ANDA. In addition, Mylan continues to place inappropriate restrictions on the fields of practice of outside counsel that might review the ANDA.

ANSWER: Denied.

23. By requiring these inappropriate restrictions, Mylan has effectively refused to provide information that would allow Sciele to confirm that Mylan's proposed generic version of Sciele's Sular® tablets 40mg is within the lawful scope of one or more claims of the '741 patent.

ANSWER: Denied.

24. Sciele is not aware of any other means of obtaining information regarding Mylan's proposed generic version of Sciele's Sular® tablets 40mg within the 45-day statutory period. In the absence of such information, Sciele resorts to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that Mylan's proposed generic version of Sciele's Sular® tablets 40mg falls within the scope of one or more claims of the '741 patent.

ANSWER: Denied.

25. On information and belief, in filing ANDA No. 79-051, Mylan has requested the FDA's approval to market generic copies of Sciele's Sular® tablets 40mg throughout the United States, including Delaware.

ANSWER: Paragraph 25 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that Mylan Pharms has filed an ANDA

seeking FDA approval for nisoldipine extended release tablets 40 mg. Mylan denies the remaining allegations of this paragraph.

26. On information and belief, if the FDA approves ANDA No. 79-051, Mylan will attempt to sell the approved proposed generic version of Sciele's Sular® tablets 40mg throughout the United States, including Delaware, before the expiration of the '741 patent.

ANSWER: Mylan admits that Mylan Pharms has filed an ANDA seeking FDA approval for nisoldipine extended release tablets 40 mg prior to the expiration of the '741 patent. Mylan denies the remaining allegations of this paragraph.

Count I

(Infringement of the '741 Patent Under 35 U.S.C. § 271(e)(2) by Mylan's proposed generic nisoldipine extended release tablets 40mg)

27. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Mylan repeats its answers to paragraphs 1-26 as set forth above.

28. On information and belief, Mylan submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed generic nisoldipine extended release tablets 40mg throughout the United States. By submitting the application, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

29. While Mylan denied infringement of the '741 patent in its Paragraph IV Letter, that Letter provides insufficient information on which Sciele may evaluate that claim. Mylan has also, to date, failed to provide ANDA No. 79-051 to allow Sciele to review the necessary information. In the absence of such information, Sciele resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its allegations of infringement and to present to the Court evidence that Mylan's proposed generic version of Sciele's Sular® tablets 40mg falls within the scope of one or more claims of the '741 patent.

ANSWER: Denied.

30. On information and belief, Sciele is entitled to a declaration whether the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic nisoldipine extended release tablets 40mg constitutes or will constitute an act of infringement of the '741 patent under 35 U.S.C. § 271.

ANSWER: Denied.

31. Sciele will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by a Court of law. Sciele does not have an adequate remedy at law.

ANSWER: Denied.

Prayer for Relief

Plaintiffs respectfully request the following relief:

a. That judgment be entered that Mylan has infringed the '741 patent under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under section 505(j) of the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's proposed generic nisoldipine extended release tablets 40mg will constitute an act of infringement of the '741 patent;

b. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Mylan's ANDA shall be a date which is not earlier than the expiration date of the '741 patent;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Mylan, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '741 patent before the expiration of said patent;

d. That damages or other monetary relief be awarded to Sciele under 35 U.S.C. § 271(e)(4)(C) as appropriate, including an accounting for any damages not included in any judgment entered after trial;

e. That this is an exceptional case under 35 U.S.C. § 285, and that Sciele be awarded reasonable attorneys' fees and costs; and

f. That this Court award such other and further relief as it may deem just and proper.

ANSWER: Mylan denies that Plaintiffs are entitled to any of the relief prayed for in paragraphs (a) through (f), above, or to any relief whatsoever, and further requests that judgment be entered in favor of Mylan, dismissing Plaintiffs' complaint with prejudice, awarding Mylan

attorneys' fees and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

Mylan further denies each allegation not specifically admitted or otherwise responded to herein.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Mylan avers and asserts the following defenses to the Complaint:

First Defense

Sciele lacks standing to bring this action for alleged infringement of the '741 patent.

Second Defense

The Court lacks subject matter jurisdiction over Sciele's claim and action for alleged infringement of the '741 patent.

Third Defense

Mylan Laboratories, Inc. (now known as Mylan Inc.) is not a proper defendant under 35 U.S.C. § 271(e)(2)(A).

Fourth Defense

The Court lacks subject matter jurisdiction over any and all claims asserted against Mylan Laboratories, Inc. (now known as Mylan Inc.).

Fifth Defense

The Complaint fails to state a claim upon which relief can be granted.

Sixth Defense

The manufacture, sale, use, offer for sale, or importation of Mylan Pharms' proposed nisoldipine product, that is the subject of its ANDA, would not infringe, either directly or indirectly, any valid and enforceable claim of the '741 patent, either literally or under the doctrine of equivalents.

Seventh Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIM

In the event and to the extent this Court has subject matter jurisdiction over this matter, Defendants/Counterclaim-Plaintiffs, Mylan Pharmaceuticals, Inc. ("Mylan Pharms") and Mylan Laboratories, Inc. (now known as Mylan Inc.)(collectively "Mylan"), assert the following Counterclaim against Plaintiff/Counterclaim-Defendants Sciele Pharma, Inc. and Sciele Pharma Cayman Ltd., (collectively, "Plaintiffs"):

The Parties

1. Mylan Pharms is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

2. Mylan Laboratories, Inc. (now known as Mylan Inc.) is a corporation organized under the laws of the State of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

3. Plaintiff Sciele Pharma, Inc. purports to be a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 5 Concourse Parkway, Suite 1800, Atlanta, Georgia 30328.

4. Plaintiff Sciele Pharma Cayman Ltd. purports to be a corporation organized and existing under the laws of the Cayman Islands with a principal place of business at Ugland House, South Church Street, Georgetown, Grand Cayman, Cayman Islands.

Jurisdiction and Venue

5. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. In the event and to the extent this Court has subject matter jurisdiction over Sciele's action, this Court also has original jurisdiction over the subject matter of this Counterclaim under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Mylan in this District, and/or because Plaintiffs conduct substantial business in this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Patent-in-Suit

9. On or about January 9, 1990, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,892,741 ("the '741 patent"), entitled "Press Coated DHP Tablets," to Andreas Ohm, Helmut Luchtenberg, Shinji Maegata and Wolfgang Opitz.

10. On or about October 22, 2007, Plaintiffs sued Mylan in this District alleging infringement of the '741 patent under 35 U.S.C. § 271(e)(2)(A).

Count I

(Declaratory Judgment of Non-Infringement of the '741 Patent)

11. Mylan re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

12. The manufacture, use, sale, offer for sale, or importation of the nisoldipine tablets that are the subject of Mylan Pharms' ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '741 patent.

13. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the nisoldipine tablets that are the subject of Mylan Pharms' ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '741 patent.

Prayer for Relief

WHEREFORE, Mylan respectfully prays for judgment in its favor and against Plaintiffs:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the nisoldipine tablets that are the subject of Mylan Pharms' ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '741 patent;

(b) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Mylan;

(c) Declaring this case exceptional and awarding Mylan its reasonable attorneys' fees and costs of this Counterclaim under 35 U.S.C. § 285; and

(d) Awarding Mylan such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Mylan hereby demands a jury trial on all issues so triable.

Dated: December 18, 2007

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